Remarks

Applicants would like to thank the Examiner for the telephone interview conducted on August 28, 2003.

The 102 Rejections

The Samejima reference

The Examiner rejected Claims 19-27 under 35 USC 102(b) as being anticipated by EP 0077956 (the Samejima reference). The Samejima reference describes, in some instances, incorporating a water-swellable polymer into an enterically coated active compound so as to promote release of the active compound at the appropriate time. However, the water-swellable material described in Samejima is not the active material itself. Samejima is using the water-swellable polymer only as an aid to his real invention, a method of making an enteric coating that works better to release an active ingredient.

By contrast, the present invention is directed to the use of a water-absorbent polymer as the active ingredient in a composition for removing fluid from the intestinal tract. In fact, Claim 19 has been amended to more clearly point out that the water-absorbent polymer is itself the active ingredient, which is not taught or suggested by Samejima. Moreover, the present invention is directed to water-absorbent polymers, as opposed to water-swellable polymers. Samejima does not teach or suggest the use of a water-absorbent polymer. The resulting composition claimed in amended Claim 19 is useful for removing fluid from the intestinal tract. Samejima does not teach or describe a composition that would be useful for removing fluid from the intestinal tract. For these reasons, amended Claim 19 of the present invention, as well as claims 20-27 which depend from Claim 19, are not anticipated by the Samejima reference.

The 103 Rejections

The Examiner rejected Claims 1, 2 and 4-27 under 35 USC 103(a) as being unpatentable over Imondi et al. (U.S. Patent No. 4,143,130) in view of Hider et al. (U.S.

Patent No. 6,132,706). Applicants respectfully disagree with the rejection for the following reasons.

The Imondi reference

Imondi teaches treating kidney stones using a water soluble polymer. Imondi is concerned with binding calcium and does not teach or suggest binding water in the intestinal tract so as to remove fluid from the intestinal tract.

By contrast, the present invention is directed to the use of water-absorbing polymers, as opposed to water-soluble polymers, for removing fluid from the intestinal tract. Water soluble polymers would not be appropriate for the present invention because they cause severe diarrhea.

Moreover, the Imondi reference teaches using the water-soluble polymer for treating kidney stones and the pain associated with kidney stones, not removal of fluid from the intestinal tract. Kidney stones are formed when the urine gets too concentrated with certain specific compounds, primarily calcium and oxalate, making calcium oxalate stones, or oxalic acid, making oxalic acid stones. There are also some patients who make calcium phosphate stones, uric acid stones, or struvite stones. None of these conditions are associated with fluid-overload states or with end stage renal disease. The first line treatment for a patient suffering from kidney stones is to markedly increase the fluid intake to try to dissolve the stones and flush them from the urinary tract. This would not be safe in a patient with fluid overload disease.

Kidney stones are a precipitate of various compounds in the ducts that collect the urine – they are not in the kidney tissue itself. Kidney stones are made of excreted compounds, so the kidney is excreting them in abundance implying healthy kidney cells or nephrons. In contrast, the aim of the present invention is the treatment of fluid overload states. When the cause of the fluid overload state is due to kidney function, it is the kidney tissue itself that is not functioning correctly. It is not related to the collecting ducts or kidney stones. The art for treating kidney disease is totally different from the art for treating kidney stones. Therefore, it would not be obvious to a person skilled in the art of treating kidney disease that the Imondi reference, which is directed at treating

kidney stones, could be applicable to fluid overload states. For all of these reasons, Claims 1, 2 and 4-27 pending in the present application are not obvious over the Imondi reference.

The Hider reference

The Hider reference describes particular set of nitrogenous compounds designed to bind phosphate and are particularly applicable for patients suffering from kidney stones. These polymers are not water absoring polymers and have nothing to do with fluid absorption – just with phosphate absorption. In particular, applicants wish to note that a "polyallylguadinidium chloride resin" described in the Hider reference is a different molecule that a "polyallylamine" as claimed in the present invention. For this reason, Claims 1, 2 and 4-27 of the present application are not obvious in view of Hider.

The Combination of the Imondi and Hider references

There might be motivation to combine the Hider and Imondi teachings because both references are concerned with the treatment of kidney stones. However, as described above, neither of these references are concerned with the treatment of kidney disease, end stage renal disease or a fluid overload state. Therefore, one of ordinary skill in the art of treating fluid overloaded or kidney disease patients would not look to the teachings of Imondi or Hider, either alone or in combination. Therefore, Claims 1, 2 and 4-27, as amended, are not obvious in view of the combination of the Imondi and Hider references.

Conclusion

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration. Applicants submit that the present application now stands in condition for allowance and request early notification thereof.

Respectfully submitted,

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